K121842

DEC 1 2 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submission correspondent:

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Scotland, UK

Device Name: ARCHITECT HbA1c Reagents and ARCHITECT HbA1c Calibrators (A-F).

Reagents:

Regulatory Description: Glycosylated hemoglobin assay

Trade Name: ARCHITECT HbA1c

Common Name: HbA1c test

Governing Regulation: 864.7470

Device Classification: Class II

Classification Panel: Hematology

Product Code: LCP

Calibrators:

Regulation Description: Calibrator

Trade Name: ARCHITECT HbA1c Calibrators (A-F)

Common Name: Calibrator

Governing Regulation: 862.1150

Device Classification: Class II

Classification Panel: Clinical Chemistry

Product Code: JIT

Legally marketed device to which equivalency is claimed:

AxSYM HbA1c Reagent and AxSYM HbA1c Standard Calibrators (A-F) (k072686)

Intended Use of Device:

Reagents:

The ARCHITECT HbA1c assay is a chemiluminescent microparticle immunoassay (CMIA) for the quantitative determination of percent hemoglobin A1c (HbA1c) in human whole blood on the ARCHITECT *i* System.

Percent HbA1c measurements are used for monitoring long term glycemic control in diabetic patients.

Calibrators:

The ARCHITECT HbA1c Calibrators are for the calibration of the ARCHITECT *i* System when used for the quantitative determination of percent haemoglobin A1c (HbA1c) in human whole blood.

Description of Device:

The ARCHITECT HbA1c assay is a two-step pre-treatment immunoassay for the quantitative determination of percent haemoglobin A1c (% HbA1c) in human whole blood using CMIA technology, with flexible assay protocols, referred to as Chemiflex.

Sample is incubated with pre-treatment reagent to lyse the red blood cells. Pre-treated sample is the incubated with magnetic microparticles with a silica surface. Hemaglobin and HbA1c in the sample bind to the silica surface of the microparticles. Following a wash cycle, anti-HbA1c acridinium-labeled conjugate is added to create a reaction mixture. Following another wash cycle, pre-trigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLUs).

The haemoglobin and HbA1c that are bound to the surface of the microparticles represents the total percentage present in the sample however, only the HbA1c result is required to determine the % HbA1c in the sample. A direct relationship exists between the amount of HbA1c in the sample and the RLUs detected by the ARCHITECT i System optics.

Comparison of Technological Characteristics:

ARCHITECT HbA1c and AxSYM HbA1c are both automated immunoassays for the quantitative determination of percent hemoglobin A1c (HbA1c).
The ARCHITECT and AxSYM systems differ in their detection methods; the ARCHITECT is a chemiluminescent microparticle immunoassay (CMIA) whereas the AxSYM is a microparticle enzyme immunoassay (MEIA).

Summary of Non-Clinical Performance:

The ARCHITECT HbA1c assay is substantially equivalent to the AxSYM HbA1c assay in terms of precision, sensitivity and measurement range (linearity) as demonstrated in the non-clinical performance data in this 510(k) submission.

The ARCHITECT HbA1c Calibrators are substantially equivalent to the AxSYM HbA1c Standard Calibrators in terms of intended use, format and % HbA1c levels.

Summary of Clinical Performance:

The ARCHITECT HbA1c assay demonstrated substantially equivalent performance to the AxSYM HbA1c assay as indicated by a method comparison study, in which a Passing & Bablock method comparison and a Pearson correlation analysis was conducted using 127 samples covering the full measuring range of the assay.

The ARCHITECT HbA1c assay demonstrated substantially equivalent performance to the AxSYM HbA1c as indicated in the method comparison study by a slope of 1.04 (95% CI: 0.97 to 1.12), an intercept of -0.07 (95% CI: -0.67 to 0.37) and a correlation coefficient (r) of 0.95 (95% CI: 0.93, 0.96).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 12, 2012

Axis-Shield Diagnostics Limited
c/o Dr. Claire I. Dora
Luna Place
The Technology Park
Dundee, Scotland, UK DD2 1XA, UK

Re: k121842
Trade/Device Name: ARCHITECT HbA1c Reagents
ARCHITECT HbA1c Calibrators

Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP, JIT
Dated: November 6, 2012
Received: November 8, 2012

Dear Dr. Dora:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121842

Device Name:

ARCHITECT HbA1c Reagents and ARCHITECT HbA1c Calibrators.

Indication For Use:

Reagents:

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health (OIR)
Evaluation and Safety

510(k) K121842